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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/085,234	02/28/2002	Sham Chopra	4769-102 US	1779

7590 10/21/2004

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EXAMINER

SPEAR, JAMES M

ART UNIT

PAPER NUMBER

1615

DATE MAILED: 10/21/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

10/085,234

**Applicant(s)**

CHOPRA, SHAM

**Examiner**

James M Spear

**Art Unit**

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 03 November 2003 & 12 August 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-64 is/are pending in the application.
- 4a) Of the above claim(s) 12-20,31-35,46-50 and 63 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-11,21-30,36-45,51-62 and 64 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All   b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)             | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

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The response and amendment filed 12 August 2004 and 03 November 2003 has been received and entered. Note the amendment list the last claim as claim 63 however it is believed that claim 63 is withdrawn from consideration as it was a non-elected claim and the last claim of the amendment is actually claim 64 as stated in applicant's remarks filed 03 November 2003. Applicant's arguments have been fully considered. Following are new grounds of rejection.

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-11, 21-30, 36-45, 51-62 and 64 are rejected under 35 U.S.C. 102(b) as being anticipated by Conte et al US 5,422,123. See examples 1-4, claim 1. The reference shows tablets with controlled-rate release of active substances. The tablets provide a constant controlled rate release just as in applicant's chemical delivery device. See Summary. The tablets comprise elements (i) and (ii) as in applicants claim 1. See figures 1-3. While the drawings show various shapes, including one that has a core having two exposed planar release surfaces as in applicants 5, the dosage forms are not considered limited to the drawings. Conte et al recognizes a defined geometrical form that is generally the form of a cylindrical tablet, however one skilled in the art would envision other geometrical forms such as squares, circles, polygons etc. because such forms are also well defined geometrical forms. See column 2, lines 33-40. The polymers used for the support include acrylates, ethylcellulose, polyvinyl alcohol,

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methacrylates as in applicant's claim 6. See column 3, lines 8-19, example 1. Pore forming elements of applicant's claim 7 are shown in column 3, lines 39-41 and include sugars such as lactose, polysaccharides such as starch, and sugar alcohols such as mannitol equivalent to those of applicant's. Polymers used to formulate the core and act as dissolution regulators as in applicant's claim 8 are shown in column 2, lines 40-55. Active agents are disclosed in the examples and include diltiazem and verapamil. The examples clearly show applicant's methods of delivering active agents such that an effective dose is provided at a constant controlled rate of release or a controlled variable rate of release as exemplified by the dissolution test of the examples.

3. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The Colombo et al reference US 4,839,177 shows a similar device as that of Conte et al for controlled release of various agents that may be of interest. Note additional platform support materials disclosed. Column 3, lines 7-12.

4. Claims 1-11, 21-30, 36-45, 51-62 and 64 are rejected.

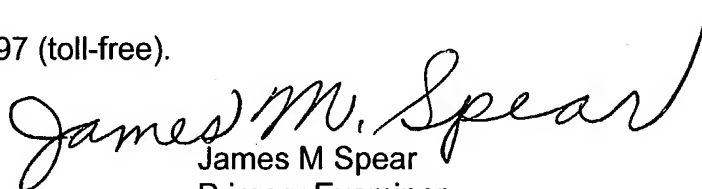
Claims 12-20, 31-35, 46-50 and 63 are withdrawn from consideration.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James M Spear whose telephone number is 571 272 0605. The examiner can normally be reached on Monday thru Friday from 6:30 AM to 3 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page, can be reached on 571 272 0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, reading "James M. Spear". The signature is fluid and cursive, with a long, sweeping tail on the letter "r".

James M Spear  
Primary Examiner  
Art Unit 1615

October 20, 2004